

**48 CFR Parts 801, 802, 808, 816, 835, and 852****RIN 2900-AQ23****VA Acquisition Regulation: Department of Veterans Affairs Acquisition****Regulation System and Research and Development****AGENCY:** Department of Veterans Affairs.**ACTION:** Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing a final rule amending the VA Acquisition Regulation (VAAR). This rulemaking revises VAAR coverage concerning Department of Veterans Affairs Acquisition Regulation System and Research and Development. It also revises affected parts concerning Definitions of Words and Terms, Required Sources of Supplies and Services, Types of Contracts and Solicitation Provisions and Contract Clauses.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Ms. Glacia A. Holbert, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 810 Vermont Avenue NW, Washington, DC 20420, (202) 697-3614. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:*Background*

VA published a proposed rule in the Federal Register at 87 FR 10158 on February 23, 2022, to amend the VAAR to implement and supplement the FAR. VA provided a 60-day comment period for the public to respond to the proposed rule and submit comments. The public comment period closed on April 25, 2022. VA received two comments from one respondent.

This rulemaking is issued under the authority of the Office of Federal Procurement Policy (OFPP) Act which provides the authority for an agency head to issue agency acquisition regulations that implement or supplement the FAR.

The VAAR has been revised to add new policy or regulatory requirements, to update existing policy, and to remove any redundant guidance where it may exist in affected parts, and to place guidance that is applicable only to VA's internal operating processes or procedures in the VAAM.

This rule adopts as a final rule the proposed rule published in the Federal Register on February 23, 2022, except for one technical non-substantive change to update terminology in accordance with FAR final rules as shown below.

Discussion and Analysis of Public Comments

The respondent alleged that the proposed rule could "...unlawfully Amend U.S. Code to facilitate illegal land use at the WLA VA Soldiers Home." This issue has no relevance to the proposed rule. The respondent also expressed dismay that Department did not extend the "Public a Comment Period on the WLA VA Soldiers Home's "Master Plan" and "Community Plan." This comment did not have any application to AQ23 which deals with the Department of Veterans Affairs Acquisition Regulation System and Research and Development. VA appreciates the respondent's interest in the rule but the two comments do not pertain to the content of the regulation. Therefore, VA is taking no action to revise the rule based on these comments.

VA proposes to make the following changes to the VAAR in this phase of its revision and streamlining initiative. For procedural guidance cited below that is proposed to be deleted from the VAAR, each section cited for removal has been considered for inclusion in VA's internal agency operating procedures in accordance with FAR 1.301(a)(2). Similarly, delegations of authority that are removed from the

VAAR will be included in the VAAM as internal agency guidance. The VAAM is being created in parallel with these revisions to the VAAR and is not subject to the rulemaking process as they are internal VA procedures and guidance. The VAAM will not be finalized until corresponding VAAR parts are finalized.

Technical Non-Substantive Changes to the Rule

This rule makes one non-substantive change to the rule to provide clarity, eliminate confusion, and to ensure compliance with the Federal Acquisition Regulation (FAR). Specifically, VA is revising the section covering the ratification of unauthorized commitments to clarify the delegation authority level for unauthorized commitments below \$25,000.

VA is revising the final rule at 801.602-3 as reflected in the amendatory text as follows:

“801.602-3, Ratification of unauthorized commitments.

(a) This section applies to unauthorized commitments, including any commitment made by a contracting officer that exceeds that contracting officer's contracting authority and unauthorized commitments made by a Government representative who lacked the authority to enter into that agreement on behalf of the Government.

(b) The approving authority and ratification official for unauthorized commitments is the HCA. This authority may be delegated to the chief of the contracting office or the equivalent for unauthorized commitments below \$25,000.”

Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive

impacts; and equity). E.O. 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this final rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

This rulemaking does not change VA's policy regarding small businesses and does not have a significant economic impact to individual businesses. The overall impact of the proposed rule would be of benefit to small businesses owned by Veterans or service-disabled Veterans as the VAAR is being updated to remove outdated guidance and to clarify and simplify the acquisition regulations VA's contractors must comply with. VA estimates no substantial cost impact to individual businesses will result from these rule updates. In total, this rulemaking does not change VA's policy regarding small businesses, does not have a substantial economic impact to individual businesses, and does not significantly increase or decrease costs small business were already required to bear when performing contracts.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal Governments or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects

48 CFR Part 801

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements.

48 CFR Parts 802, 808, and 816

Government procurement.

48 CFR Part 835

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 27, 2022, and authorized the undersigned to sign and submit the document to

the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulations Development Coordinator,
Office of Regulation Policy & Management,
Office of General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 48 CFR chapter 8 as follows:

1. Part 801 is revised to read as follows:

PART 801—DEPARTMENT OF VETERANS AFFAIRS ACQUISITION REGULATION SYSTEM

Sec.

801.000 Scope of part.

Subpart 801.1—Purpose, Authority, Issuance

801.101 Purpose.

801.103 Authority.

801.104 Applicability.

801.104-70 Exclusions.

801.106 OMB approval under the Paperwork Reduction Act.

Subpart 801.3—Agency Acquisition Regulations

801.301 Policy.

801.304 Agency control and compliance procedures.

Subpart 801.4—Deviations from the FAR

801.403 Individual deviations.

801.404 Class deviations.

Subpart 801.6—Career Development, Contracting Authority, and Responsibilities

801.601 General.

801.602-3 Ratification of unauthorized commitments.

801.604 Contracting Officer's Representative (COR).

Authority: 38 U.S.C. 8123; 38 U.S.C. 8153; 38 U.S.C. 8303; 40 U.S.C. 121(c); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

801.000 Scope of part.

This part includes general Department of Veterans Affairs (VA) Acquisition Regulation (VAAR) policies, including information regarding the maintenance and administration of the VAAR, acquisition policies and practices, and procedures for deviation from the VAAR and the Federal Acquisition Regulation (FAR).

Subpart 801.1—Purpose, Authority, Issuance

801.101 Purpose.

(a) VA established the VAAR to codify and publish uniform policies and procedures for VA's acquisition of supplies and services, including construction.

(b) The VAAR implements and supplements the FAR.

801.103 Authority.

The VA issues the VAAR under the authority of 41 U.S.C. 1707 and 48 CFR 1.301 through 1.304, and other authorities as cited.

801.104 Applicability.

The FAR and the VAAR apply to all FAR-based VA actions using appropriated funds unless otherwise specified in this regulation. Supply Fund monies (38 U.S.C. 8121) and General Post Funds (38 U.S.C. 8302) are appropriated funds.

801.104-70 Exclusions.

(a) *Restricted gifts.* The FAR and VAAR do not apply to purchases and contracts that use General Post Funds if using the FAR and the VAAR would infringe upon a donor's right to specify the exact item to be purchased and/or the source of supply (38 U.S.C. 8303).

(b) *Procurement of prosthetic appliances.* The VA may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the VA may determine to be proper, without regard to any other provision of law (38 U.S.C. 8123).

(c) *Sharing of health-care resources.* (1) To secure health-care resources which otherwise might not be feasibly available, or to effectively utilize certain other health-care resources, the VA may, when the VA determines it to be in the best interest of the prevailing standards of the Department medical care program, make arrangements, by contract or other form of agreement for the mutual use, or exchange of use, of health-care resources between Department health-care facilities and any health-care provider, or other entity or individual.

(2) The VA may enter into a contract or other agreement under paragraph (c)(1) of this section if such resources are not, or would not be, used to their maximum effective capacity.

(3)(i) If the health-care resource required is a commercial service, the use of medical equipment or space, or research, and is to be acquired from an institution affiliated with the Department in accordance with 38 U.S.C. 7302, including medical practice groups and other entities associated with affiliated institutions, blood banks, organ banks, or research centers, the VA may make arrangements for acquisition of the resource without regard to any law or regulation (including any Executive order, circular, or other administrative policy) that would otherwise require the use of competitive procedures for acquiring the resource.

(ii) If the health-care resource required is a commercial service or the use of medical equipment or space, and is not to be acquired from an entity described in paragraph (c)(3)(i) of this section, any procurement of the resource may be conducted without regard to any law or regulation that would otherwise require the use of competitive procedures for procuring the resource, but only if the procurement is conducted in accordance with the simplified procedures prescribed in part 873. (38 U.S.C. 8153).

801.106 OMB approval under the Paperwork Reduction Act.

See VA Acquisition Manual (VAAM) M801.106 for a list of the information collection and recordkeeping requirements contained in this part that have been approved by the Office of Management and Budget.

Subpart 801.3—Agency Acquisition Regulations

801.301 Policy.

(a)(1) VA implementation and supplementation of the FAR is issued in the Veterans Affairs Acquisition Regulation (VAAR) under authorization and subject to the authority, direction, and control of the Secretary of Veterans Affairs. The VAAR contains—

- (i) Requirements of law;
- (ii) Agency policies;
- (iii) Delegations of FAR authorities;
- (iv) Deviations from FAR requirements; and
- (v) Policies/procedures that have a significant effect beyond the internal operating procedures of VA or a significant cost or administrative impact on contractors or offerors.

(2) Relevant internal procedures, guidance, and information (PGI) that do not meet the criteria in paragraph (a)(1) of this section are issued in the Veterans Affairs Acquisition Manual (VAAM).

(b) [Reserved]

801.304 Agency control and compliance procedures.

The Principal Executive Director of VA's Office of Acquisition, Logistics and Construction is designated as the Department's Chief Acquisition Officer. The Executive Director for the Office of Acquisition and Logistics (OAL) is designated as the Department's Senior Procurement Executive (SPE). The SPE is responsible for amending the VAAR for compliance with FAR 1.304.

Subpart 801.4—Deviations from the FAR

801.403 Individual deviations.

The SPE may authorize individual deviations from the FAR and VAAR in accordance with FAR 1.403 when an individual deviation is in the best interest of the Government.

801.404 Class deviations.

The SPE may authorize class deviations from the FAR and VAAR when a class deviation is in the best interest of the Government.

Subpart 801.6—Career Development, Contracting Authority, and Responsibilities

801.601 General.

(a) The Senior Procurement Executive is granted the authority to appoint and terminate contracting officers. This authority is further delegated to the heads of the contracting activities (HCA) and others as appropriate. The SPE may also delegate authority to execute, award, and administer contracts, purchase orders, and other agreements to other VA officials, such as HCAs and contracting officers. All delegations of authority will be made in writing.

(b) HCAs may authorize the use of ordering officers to order supplies and services in accordance with the ordering limits identified in the contract or agreement or the specific ordering guide. Ordering officers shall be delegated in writing. The written delegation must be specific to the contract or agreement and articulate the limitations of the delegated authority. Ordering officers shall only place orders against the contract or agreement if it is awarded to a single awardee. Ordering officers may not negotiate contract terms and conditions, determine price reasonableness, or determine best value. If the contracting officer determines prior to award that ordering officers will be authorized to place orders against a contract or agreement, the contracting officer will furnish the contractor with the names of individuals delegated ordering officer authority by separate letter upon issuance of the contract.

801.602-3 Ratification of unauthorized commitments.

(a) This section applies to unauthorized commitments, including any commitment made by a contracting officer that exceeds that contracting officer's contracting authority and unauthorized commitments made by a Government representative who lacked the authority to enter into that agreement on behalf of the Government.

(b) The approving authority and ratification official for unauthorized commitments is the HCA. This authority may be delegated to the chief of the contracting office or the equivalent for unauthorized commitments below \$25,000.

801.604 Contracting Officer's Representative (COR).

When the contracting officer intends to designate a Contracting Officer's Representative for a solicitation or contract, the contracting officer must include the clause in 852.201-70, Contracting Officer's Representative, in the solicitation and contract.

PART 802—DEFINITIONS OF WORDS AND TERMS

2. The authority citation for part 802 continues to read as follows:

Authority: 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301-1.304.

Subpart 802.1—Definitions

3. Section 802.101 is amended by adding the definition "Ordering officer" in alphabetical order to read as follows:

802.101 Definitions.

* * * * *

Ordering officer means the VA official authorized to order supplies and services against a FAR-based contract or agreement in accordance with the ordering limits identified in the contract or agreement or the specific ordering guide in accordance with 801.601(b).

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PART 808—REQUIRED SOURCES OF SUPPLIES AND SERVICES

4. The authority citation for part 808 continues to read as follows:

Authority: 38 U.S.C. 8127-8128; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 808.4—Federal Supply Schedules

5. Add section 808.470 to read as follows:

808.470 Ordering Officers

In accordance with 801.601, when authorized, ordering officers may place orders for supplies and services against agreements or task or delivery orders established by a contracting officer against Federal Supply Schedules within the ordering limits identified in the contract or agreement or the specific ordering guide when funding is available. Ordering officers shall only place orders against the order or agreement if it is awarded to a single awardee. The contracting officer that awarded the Blanket Purchase Agreements (BPA) or order will provide the contractor a list of authorized ordering officers. Any modifications to the agreement or order must be performed by a contracting officer.

PART 816—TYPES OF CONTRACTS

6. The authority citation for part 816 continues to read as follows:

Authority: 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 816.5—Indefinite-Delivery Contracts

7. Add section 816.570 to read as follows:

816.570 Ordering officers.

In accordance with 801.601, when authorized, ordering officers may place orders for supplies and services against established Indefinite-Delivery Contracts within the ordering limits identified in the contract or the specific ordering guide when funding is available. Ordering officers shall only place orders against the contract if it is awarded to a single awardee. When a contracting officer appoints an ordering officer in writing after award, the contracting officer will furnish the contractor with an updated list of individual ordering officers authorized to place orders against the contract. Ordering officers may not negotiate contract terms and conditions, determine price reasonableness, or determine best value.

8. Part 835 is added to subchapter F to read as follows:

PART 835—RESEARCH AND DEVELOPMENT CONTRACTING

Sec.

835.001-70 Veterans Affairs (VA) definitions.

835.003-70 VA policy.

835.003-71 Research misconduct.

835.003-72 Protection of human subjects.

835.003-73 Animal welfare.

835.003-74 Facilities.

835.003-75 Acknowledgement of support and disclaimer.

835.010 Scientific and technical reports.

Authority: 38 U.S.C. 7303; 40 U.S.C. 121(c); 41 U.S.C. 1702 and 48 CFR 1.301 through 1.304.

835.001-70 Veterans Affairs (VA) definitions.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

Research impropriety refers to noncompliance with the laws, regulations, and policies regarding human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. It does not encompass improper procedures or conduct in areas outside of the mandate of the Office of Research Oversight (ORO) (e.g., waste, fraud, abuse, or fiscal mismanagement).

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

VA facility means a component of the VA national health care system, such as a VA Medical Center, VA Health Care System, or VA Medical and Regional Office Center.

835.003-70 VA policy.

(a) Pursuant to 38 U.S.C. 7303, VA is authorized to carry out a program of medical research in connection with the provisions of medical care and treatment to Veterans.

(b) The Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office that advises the Under Secretary for Health on all compliance matters related to—

- (1) Human subject protections;
- (2) Laboratory animal welfare;
- (3) Research safety;
- (4) Research laboratory security;
- (5) Research information security;
- (6) Research misconduct; and
- (7) Other research improprieties.

835.003-71 Research misconduct.

The contracting officer shall insert the clause at 852.235-70, Research Misconduct, in all research and development (R&D) solicitations and contracts.

835.003-72 Protection of human subjects.

The contracting officer shall insert the clause at 852.235-71, Protection of Human Subjects, in all research and development (R&D) solicitations and contracts.

835.003-73 Animal welfare.

The contracting officer shall insert the clause at 852.235-72, Animal Welfare, in all research and development (R&D) solicitations and contracts.

835.003-74 Facilities.

If the contracting officer determines that the facilities to be assigned to perform effort on a research and development (R&D) contract are critical to the success of the R&D effort, the contracting officer shall insert the clause at 852.235-73, Facilities, in the solicitation and contract.

835.003-75 Acknowledgement of support and disclaimer.

The contracting officer shall insert the clause at 852.235-74, Acknowledgement of Support and Disclaimer, in all research and development (R&D) solicitations and contracts.

835.010 Scientific and technical reports.

The contracting officer shall insert the clause at 852.235-75, Scientific and Technical Reports, in all research and development (R&D) solicitations and contracts.

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

9. The authority citation for part 852 continues to read as follows:

Authority: 38 U.S.C. 8127-8128 and 8151-8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3), 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

10. Section 852.235-70 is added to read as follows:

852.235-70 Research Misconduct.

As prescribed at 835.003-71, insert the following clause:

RESEARCH MISCONDUCT (DEC 2022)

(a) The Contractor is responsible for maintaining the integrity of research performed pursuant to this contract award including the prevention, detection and remediation of research misconduct as defined in 835.001-70.

(b) The Contractor shall notify the Contracting Officer within 7 business days of any research misconduct allegations received by the facility concerning this contract award.

(c) The Contractor shall conduct an initial inquiry into any allegation of research misconduct. If the Contractor determines that there is sufficient evidence to proceed to an investigation, the Contractor shall notify the Contracting Officer and, unless otherwise instructed shall—

(1) Conduct an investigation to develop a complete factual record and an examination of such record leading to either a finding of research misconduct and an

identification of appropriate remedies, or a recommendation that no further action is warranted;

(2) When the investigation results in a research misconduct finding, ensure the matter is adjudicated by a responsible official who was not involved in the inquiry or investigation and is organizationally separated from the element which conducted the investigation. The adjudication shall include a review of the investigation record and a recommendation of appropriate corrective actions and sanctions; and

(3) When an investigation is complete, the Contractor shall forward to the Contracting Officer a copy of the evidentiary record, the investigative report, any recommendations made to the Contractor's adjudicating official, the adjudicating official's recommendation and notification of any proposed corrective action, and the subject's written response, if any. The Contracting Officer will review the documentation to determine whether the proposed corrective action can proceed.

(d) The VA may elect to act in lieu of the Contractor in conducting an inquiry or investigation into an allegation of research misconduct if the Contracting Officer finds that—

(1) The research organization is not prepared to handle the allegation in a manner consistent with this clause and it is believed it cannot reasonably conduct the inquiry;

(2) VA involvement is necessary to ensure the public health, safety, and security, or to prevent harm to the public interest; or

(3) The allegation involves possible criminal misconduct.

(e) The Contractor shall provide safeguards for information received and protect informants, witnesses and respondents of allegations as follows:

(1) The Contractor shall provide safeguards to ensure that individuals may bring allegations of research misconduct made in good faith to the attention of the Contractor

without suffering retribution. Safeguards include: protection against retaliation; fair and objective procedures for examining and resolving allegations; and diligence in protecting positions and reputations.

(2) The Contractor shall also assure the respondent that their rights are protected and that the mere filing of an allegation of research misconduct will not result in an adverse action. Safeguards include timely written notice regarding substantive allegations against them, a description of the allegations and reasonable access to any evidence submitted to support each allegation. Respondents must be given the opportunity to prepare a response to an allegation and notice of any findings of research misconduct.

(f) *Objectivity and expertise.* The Contractor shall select individual(s) to inquire, investigate, and adjudicate allegations of research misconduct who have appropriate expertise and have no unresolved conflict of interest. The individual(s) who conducts the adjudication must not be the same individual(s) who conducted the inquiry or investigation and must be separate organizationally from the element that conducted the inquiry or investigation.

(End of clause)

11. Section 852.235-71 is added to read as follows:

852.235-71 Protection of Human Subjects.

As prescribed at 835.003-72, insert the following clause:

PROTECTION OF HUMAN SUBJECTS (DEC 2022)

(a) Research involving human subjects is not permitted under this award unless expressly authorized in writing by the Contracting Officer. Such authorization will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.

(b) The Federal Policy for the Protection of Human Subjects (the “Common Rule”), adopted by VA (see 38 CFR part 16), requires Contractors to maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a “human subject” as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term “research” means a systematic investigation, including research development and/or testing and evaluation, designed to develop or contribute to generalized knowledge. The Common Rule also sets forth categories of research that may be considered exempt from 15 CFR part 27. These categories may be found at 15 CFR 27.101.

(c) Should research involving human subjects be included in the proposal, prior to issuance of an award, the Contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that the Contractor has established a relationship with an appropriate Institutional Review Board (“cognizant IRB”). An appropriate IRB is one that is located within the United States and within the community in which the research will be conducted;

(2) Documentation to verify that the cognizant IRB possesses a valid registration with the United States Department of Health and Human Services' Office for Human Research Protections (“OHRP”);

(3) Documentation to verify that the Contractor has a valid Federal-wide Assurance (FWA) issued by OHRP.

(d) Prior to starting any research involving human subjects, the Contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval. This documentation may include:

(1) Copies of the research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule (Note: this option is not available for activities that fall under 45 CFR part 46, subpart C).

(e) Additionally, if the Contractor modifies a research protocol, questionnaire, survey, advertisement, or informed consent form approved by the cognizant IRB, the Contractor shall submit a copy of all modified material along with documentation of approval for said modification by the cognizant IRB to the Contracting Officer for institutional review and approval. The Contractor shall not implement any IRB approved modification without written approval by the Contracting Officer.

(f) No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(g) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agency or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and

undertakings and the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(h) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements, the Contracting Officer may immediately suspend the research and further payments under this contract until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete the corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract and the Contractor's name may be removed from the list of those Contractors with approved Department of Health and Human Services Human Subject Assurances.

(End of clause)

12. Section 852.235-72 is added to read as follows:

852.235-72 Animal Welfare.

As prescribed in 835.003-73, insert the following clause:

ANIMAL WELFARE (DEC 2022)

(a) The Contractor shall—

(1) Use the Veterans Affairs (VA), Office of Research Oversight (ORO)

Laboratory Animal Welfare Checklist;

(2) Comply with the United States Department of Agriculture (USDA) Animal Welfare Act and Animal Welfare Regulations at https://www.aphis.usda.gov/animal_welfare, and the Animal Welfare Information

Center's (AWIC) information for improved animal care and use in research, testing, and teaching provided at <https://www.nal.usda.gov/awic>;

(3) Develop and provide to the Contracting Officer a written plan of providing adequate veterinary care to laboratory animals, including—

(i) The frequency of visits; and

(ii) Provisions for after-hours, weekend and holiday veterinary coverage.

(b) The Contracting Officer may immediately suspend the work by issuance of a stop work order and suspend further payments under this contract for failure to comply with the requirements of this clause.

(c) The suspension will stay in effect until the Contractor complies with the requirements. Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this contract.

(d) The Contractor shall include the substance of this clause, in all subcontracts involving research and development, testing, evaluation or training that use live vertebrate animals.

(End of clause)

13. Section 852.235-73 is added to read as follows:

852.235-73 Facilities.

As prescribed at 835.003-74, insert the following clause:

FACILITIES (DEC 2022)

(a) The facilities specified in the contract are considered essential to the work being performed under this contract. Therefore, prior to removing, replacing, or diverting any of the listed or specified facilities, the Contractor shall—

(1) Notify the Contracting Officer in writing; and

(2) Submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the potential impact on this contract.

(b) The Contractor shall make no removal, replacement or diversion of facilities without the Contracting Officer's written consent.

(End of clause)

14. Section 852.235-74 is added to read as follows:

852.235-74 Acknowledgement of Support and Disclaimer.

As prescribed at 835.003-75, insert the following clause:

ACKNOWLEDGEMENT OF SUPPORT AND DISCLAIMER (DEC 2022)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material based on or developed under this contract, stated in the following terms: This material is based upon work supported by the (name of contracting agency) under this VA contract.

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer:

Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the VA.

(End of clause)

15. Section 852.235-75 is added to read as follows:

852.235-75 Scientific and Technical Reports.

As prescribed at 835.010, insert the following clause:

SCIENTIFIC AND TECHNICAL REPORTS (DEC 2022)

The Contractor shall submit an electronic copy of the approved scientific technical reports, not a summary, delivered under this contract to the National Technical Information Service (NTIS) as delineated at FAR 35.010.

(End of clause)

852.270-1 [Redesignated]

16. Redesignate Section 852.270-1 as section 852.201-70 and revise newly redesignated section 852.201-70 to read as follows:

852.201-70 Contracting Officer's Representative.

As prescribed in 801.604, insert the following provision:

CONTRACTING OFFICER'S REPRESENTATIVE (DEC 2022)

The Contracting Officer reserves the right to designate representatives to act for him/her in furnishing technical guidance and advice or generally monitor the work to be performed under this contract. Such designation will be in writing and will define the scope and limitation of the designee's authority. A copy of the designation letter shall be furnished to the Contractor.

(End of provision)